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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/751,769	12/29/2000	Judith K. Gwathmey	JGT-002	5078

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EXAMINER

SAUNDERS, DAVID A

ART UNIT PAPER NUMBER

1644

DATE MAILED: 08/12/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.



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69151-769
APPLICATION NUMBER FILING DATE FIRST NAMED APPLICANT ATTY. DOCKET NO.

EXAMINER

ART UNIT PAPER NUMBER

DATE MAILED:

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☒ Responsive to communication(s) filed on 4/24/02
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-29 is/are pending in the application.
- Of the above, claim(s) 13-29 is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-12 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☒ The proposed drawing correction, filed on 4/16/01 is ☒ approved ☐ disapproved.
BY THE DRAFTSMAN
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

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Claims 1-29 are pending.

Applicant's election without traverse of Group I (claims 1-12) in Paper No. 6 is acknowledged.

> The disclosure is objected to because of the following informalities: at page 1, there is no reference to provisional application 60/173,924.

Appropriate correction is required.

> Claim 5 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 5 requires that the liposome be multilamellar or unilamellar. As far as the examiner knows, any liposome is either multilamellar or unilamellar. Claim 5 thus fails to narrow the scope of base claim 4 in any way.

> Claims 8 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 is unclear as to where the antibodies are -- within the liposome, or at its surface?

In claim 11, "the liposome lamellae" lack antecedent basis.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

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(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2., 4-7 and 9-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Lau et al. (1981, ref A5).

Lau et al. (1981) teach (abstract) encapsulation of desferrioxamine (DF) in multilamellar or unilamellar liposomes, which are prepared with or without a galactosyl moiety. The liposomes have diameters of 0.5 or 0.08 micrometers; which are within the range of instant claim 6.

Lau et al. teach 59 Fe labeled liposomes (page 507, second full par.), in accord with instant claim 9.

The features of instant claims 11 and 12 are considered inherent to the multilamellar and unilamellar liposomes of Lau et al., absent evidence to the contrary.

Regarding claim 7, the preparation of liposomes (par. spanning pages 506-507) uses charged lipids.

Claims 1-2, 4-7, and 9-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Rahman (1981, ref A7).

Rahman teach multilamellar and unilamellar liposomes with encapsulated DF. these can be prepared with a galactosyl moiety. Diameters are 0.5 and 0.8 micrometers. See page 212, first full paragraph.

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The liposomes were prepared with charged lipids and labeled with ⁵⁹Fe. See page 222, second full paragraph and the paragraph spanning pages 222-223.

Claims 1-2, 4-7 and 9-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Rahman et al. (1980, ref A8).

Rahman et al. (1980) disclose the same liposomes as Rahman (1981) noted supra.

Claims 1-2, 4-5 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Hopkins (ref A2).

Hopkins teaches liposomes with entrapped DF. Thus claims 1-2 and 4 are anticipated. Claim 5 is rejected since any liposome is either multilamellar or unilamellar. Claim 7 is included because charged lipids are used (page 503).

Claims 1-2, 4-5 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Blake (E.P. 0,068,314).

Blake teaches liposomes containing DF, (pages 5, 7). The liposomes were prepared with various charged lipids (pages 10-11), and were either multilamellar or unilamellar (page 11).

Claims 1-7 are rejected under 35 U.S.C. 102(a) as being anticipated by Postma et al. (ref A6).

Postma et al. show preparation of liposomes containing desferrioxamine (DF)). The liposomes were prepared with charged lipids (page 52, col. 2). Claim 5 is rejected, since all liposomes are deemed to be either multilamellar or unilamellar. The size varied from 300-500 nanometers (page 52, col. 2). As far as it is possible to determine from the reference the range of

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1 mM to 100 mM recited in instant claim 3 was achieved; the paragraph spanning pages 52-53, shows that, after diluting a sample of lysed liposomes Ca. 4x, there was a linear fluorescence measurement from 15-80 mM of DFO, which upon multiplication by four gives 60-240 mM as the intraliposomal concentration of the DFO.

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of Lau et al. (1981), Rahman, Rhaman et al. or Hopkins in view of applicant's admitted state of the art and Kilbanov et al. (ref A3).

Each primary reference has been noted supra for preparing liposomes containing DF for use in the treatment of iron overload. Applicant has admitted that iron overload was known to affect the heart (pages 1-2). Applicant is reminded of his duty to disclose what this art is.

Klibanov et al. teach (page 60, col. 2) that drug loaded liposomes may be targeted to the heart by anti-myosin antibodies. Since iron overloading was known to damage the heart, it would have

*applicant
failed to
discuss
any
art.*

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been obvious to target the liposomes of any of the primary references, via antibodies against myosin as taught by Klibanov et al.

Klibanov et al. also teach the further feature that it is known to prepare liposomes having labeled lipid components -- i.e. 111 In-DPTA-SA, in order to follow the in vivo distribution of liposomes. Thus the limitations of instant claim 10 would have been obvious.

Claims 1-7 and 10-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Allen et al. (4,920,016) in light of Lau et al. and Ritter et al. (5,854,007).

Allen et al. teach multilamellar liposomes (MLVs) containing desferal (same as desferrioxamine -- e.g. see Lau et al. (A4 at page 807 or A5 at page 506). See col. 12, lines 21-41 and col. 16, lines 45-53. The concentration of desferal and the liposome sizes disclosed therein are consistent with instant claims 3 and 6. Claim 7 is anticipated, since Example 9 (col. 17) shows that such liposomes were prepared with negative charged lipid components. Claim 10 is anticipated since the liposomes bearing GM1 contain a galactosyl moiety; see structure of GM1 shown by Ritter et al. at col. 1, lines 45-53. Claim 11 is anticipated since the encapsulated desferal would inherently be so in either recited manner.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunder, Ph.D., whose telephone number is (703) 308-3976. The examiner can normally be reached on Monday-Thursday from 8:00 a.m. to 5:30 p.m. The examiner can also be reached on alternate Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on (703) 308-3973. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

D. Saunders:jmr

July 25, 2002

David A Saunders
DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT 182/644